IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re: W.R. GRACE & CO., *et al.*, DEBTORS	Chapter 11 Case No. 01-1139 (JKF) Jointly Administered
W.R. GRACE & CO., *et al.*; OFFICIAL COMMITTEE OF ASBESTOS PERSONAL INJURY CLAIMANTS; ASBESTOS PI FUTURE CLAIMANTS' REPRESENTATIVE; OFFICIAL COMMITTEE OF EQUITY SECURITY HOLDERS;	Objection Deadline: 9/1/09 Hearing Date & Time: 9/8/09 at 11:00 A.M. Pittsburgh, Pennsylvania

PLAN PROPONENTS' MOTION IN LIMINE TO EXCLUDE EXPERT TESTIMONY OF ALAN WHITEHOUSE, M.D., ARTHUR FRANK, M.D., CRAIG MOLGAARD, PH.D., AND TERRY SPEAR, PH.D.

The Plan Proponents respectfully request that the Court exclude the testimony of Alan Whitehouse, M.D., Arthur Frank, M.D., Craig Molgaard, Ph.D., and Terry Spear, Ph.D., who have been proffered as experts by the Libby Claimants. These experts' opinions simply are not relevant to any issue in these proceedings. Moreover, by their own admission, their opinions in this case suffer from several defects that render them fundamentally flawed and unreliable.

The fundamental issue raised by the Libby Claimants in these proceedings is whether the Proposed Plan imposes unequal or discriminatory treatment. Under the Bankruptcy Code, the

Plan must resolve claims on an equal basis. *See* 11 U.S.C. §§ 524(g)-1123(a)(4); *Begier v. IRS*, 496 U.S. 53, 58 (1990). "Equal" treatment requires that all personal injury claims be resolved through the same process. *In re Central Med. Ctr., Inc.*, 122 B.R. 568, 575 (Bankr. E.D. Mo. 1990); *see also In re Dow Corning Corp.*, 255 B.R. 455, 497-98 (E.D. Mich. 2000). The Proposed Plan and Asbestos PI TDP ("TDP") establish just such a process comprised of expedited review, individual review, and if necessary, jury trial. This process is not only consistent with the Bankruptcy Code, but is essential to the proper working of a Section 524(g) trust, which must dispense compensation to literally thousands of claimants with minimal transaction costs.

Because the process established by the Plan is the same for all claimants, by definition there can be no discriminatory treatment. Nonetheless, the Libby Claimants assert otherwise. In support of this assertion, the Libby Claimants seek to introduce expert testimony from Dr. Alan Whitehouse, Dr. Arthur Frank, Dr. Craig Molgaard, and Dr. Terry Spear. The Libby Claimants bear the burden under the Federal Rules of demonstrating that the expert evidence they submit in these proceedings is both relevant to this issue and reliable. *See* Bankr. R. 9017 (incorporating Federal Rules of Evidence); Fed. R. Evid. 702. The Libby Claimants can satisfy neither requirement.

First, their experts address the wrong issues, and thus the testimony from them simply is not relevant. The issue here is *not* whether there are some people whose doctors believe they are sick but who do not receive compensation under the TDP's expedited review criteria. Rather, the ultimate issue is whether the TDP criteria *discriminate* against them versus other claimants. None of the Libby experts even purport to address this fundamental question -- and they admit it. Instead, they seek to criticize the TDP in a way that does not address any confirmation standard.

Second, the expert opinions the Libby Claimants seek to introduce are fundamentally flawed and unreliable. As their own experts acknowledge, the suggestion that the Libby Claimants have a distinct disease is an untested "hypothesis" that lacks any scientific support. Moreover, even the "analyses" that lead to various hypotheses advanced by the Libby Claimants lack foundation and are riddled with profound scientific error. And the expert opinions the Libby Claimants seek to introduce regarding rates of disease, aside from being irrelevant, also are not based on proper methodology and are corrupted by the very same bad science that purports to find that they have "distinct" medical conditions. The Federal Rules make clear that such flawed and unreliable opinions must be excluded.

BACKGROUND

The Libby Claimants rely primarily on the opinions of Dr. Alan Whitehouse, a physician from Spokane, Washington who has treated patients in Libby, Montana. Claimants cite Dr. Whitehouse's opinions throughout their Trial Brief (Libby Tr. Br. (Docket No. 22439) at 2, 12-15, 22), and indeed recently represented that his opinions constitute "the heart of [their] case -- in these confirmation proceedings" (7/27/09 Tr. at 160). Accordingly, each of their experts, in turn, specifically relies on Dr. Whitehouse's analysis. (*See* 12/23/08 Frank Report at 7-10, 12 (Ex. 1); 5/18/09 Molgaard Report at 2-10, 12-14 (Ex. 2); 12/29/08 Spear Report at 8-9, 26 (Ex. 3).)

A. Dr. Whitehouse

Dr. Whitehouse has testified on behalf of Libby Claimants since at least the 1990s, and has been the source of the Libby Claimants' early contention in these proceedings that there is a "distinct pattern" present in pleural disease in the Libby group of claimants caused by exposure to amphibole asbestos in Libby. (June 15, 2005 General Aff. of Dr. Alan C. Whitehouse at 12 (Ex. 4).) Opinions regarding patterns or groups of people and causation are the essence of epidemiology. Yet, a federal court applying *Daubert* principles has already determined that Dr.

Whitehouse is not qualified to address matters of epidemiology. (*See United States v. W.R. Grace*, Doc. No. 1103, Apr. 21, 2009 Order at 4 ("Dr. Whitehouse does not posses specialized knowledge in the field of epidemiology.").) Accordingly, the court held that Dr. Whitehouse's "opinion testimony on the future pattern of disease and general causation is therefore inadmissible under Rules 701(c) and 702." (*See id.*)

Dr. Whitehouse's analysis has gone backwards, not forwards, since Judge Molloy's ruling. In his December 2008 expert report, as before, Dr. Whitehouse purported to offer epidemiological opinions based upon a patient population of 1,800 individuals at the Center for Asbestos Related Disease ("CARD") Clinic in Libby, Montana. (12/29/08 Whitehouse Report at 27 (Ex. 5).) Specifically, he opined that all 1,800 had asbestos-related diseases and that all 1,800 cases of asbestos disease were "*due to* exposure to Libby asbestos with its source in W.R. Grace and Zonolite Co. mining and other activities." (*Id.*) Dr. Whitehouse purported to extract sub-groups of his patient population, and compared these self-selected groups of individuals to cohorts that were published in the peer-reviewed literature and purported to draw "epidemiological" inferences and conclusions based on these comparisons. (*Id.* at 23.)

What has happened since then? Dr. Whitehouse has taken the opinions that he rendered based upon the *1,800* patients and *by fiat* said that his basis was a smaller group of people, this being driven solely by litigation demands rather than scientific or medical demands. During Dr. Whitehouse's March 19, 2009 deposition, he relied, as before, upon the medical records of his *entire 1,800 patient population* in reaching his expert opinions, and testified that he had to rely on *all* such individuals -- he could not compartmentalize some of the patients and exclude them from his consideration. (3/19/09 Whitehouse Dep. at 68-69 (Ex. 6).) However, it was apparent that Dr. Whitehouse had not produced the medical records for all of these individuals, and after

extensive motion practice, the Court issued an order requiring Dr. Whitehouse to produce the medical records for the 850+ individuals whose records had yet to be produced. (5/27/09 Order (Docket No. 21874).) That same order provided that if Dr. Whitehouse did not produce the additional records for these individuals, he would be barred from offering opinions relating to them at the confirmation hearing. (*Id.* at 2.) Claiming that he was unable to produce the medical records, Dr. Whitehouse simply asserted that his opinions were now based upon 950, rather than 1,800 patients. (6/16/09 Whitehouse Dep. at 86 (Ex. 7).)

Matters got even worse. In his June deposition he sought to base his opinions upon *79 people* whose medical evidence he claimed could be "extrapolated" to the legally-driven group of 950 patients. He produced not even one document to support his contention. (*See* 6/16/09 Whitehouse Dep. at 315-16 (Ex. 7).) It was pure *ipse dixit*.

All of this has stood in service of opinions that he now admits do not address the issue here: Are Libby patients being treated differently than non-Libby patients? Under oath, Dr. Whitehouse acknowledged that he had not analyzed this issue:

> Q. .... Is it accurate that you've not done any scientific analysis of diffuse pleural thickening in any patient population outside of Libby?
>
> A. That is true.

(6/16/09 Dr. Whitehouse Dep. at 115 (Ex. 7).)

Indeed, Dr. Whitehouse even walked away from his long-expressed tenet and acknowledged that the Libby Claimants have "basically the same disease" as individuals in other populations:

> Q. Dr. Frank has told us under oath that he does not believe that there is a different disease or a special disease or form of disease, pleural disease in Libby. It's just the same disease? Would you agree with that?
>
> A. Well, I would agree that it's basically the same disease that has been occasionally seen in chrysotile.

(6/16/09 Whitehouse Dep. at 203 (Ex. 7).)

B. Dr. Frank

In an effort to salvage and legitimize Dr. Whitehouse's subjective assertions, the Libby Claimants retained a physician specializing in occupational medicine, Dr. Arthur Frank. Dr. Frank is a professional testifying expert, having been retained in literally thousands of matters related to asbestos disease and *having sat for well over a thousand depositions*. (6/5/09 Frank Dep. at 113-14 (Ex. 8).) In this case, he adopted the flawed data sets used by Whitehouse. Out of the 1,800 patients in Dr. Whitehouse's patient group, Dr. Frank reviewed about 80 x-rays *selected by Dr. Whitehouse* from thousands of x-rays in his patients' files. Dr. Frank has not examined any of the Libby Claimants on whose behalf he is appearing, and he has done no independent analysis of any data.

He then adopted Whitehouse's opinions only to abandon them in his deposition. (*See* 12/23/08 Frank Report at 12 (Ex. 1).) Under oath, Dr. Frank backed away from Dr. Whitehouse. Specifically, he testified that the Libby Claimants' diseases were "no different" than the diseases of people exposed to asbestos outside of Libby:

> Q. Well, the diseases that people in Libby suffer are no different than the diseases people outside of Libby suffer, is that correct?
>
> A. It's the same set of asbestos-related diseases.

(6/5/09 Frank Dep. at 195 (Ex. 8).)

As to the critical issue before the Court here, alleged discrimination, he acknowledged that no one had done *any* analysis that would show that the TDP criteria "have any kind of disproportionate effect on people with diffuse pleural disease at Libby":

> Q. And have you done the analysis about whether the TDP category Roman IV B would have any kind of disproportionate effect on people with diffuse pleural disease at Libby?

A. I have not done that kind of analysis.

Q. Are you aware of anybody who has?

A. No.

(6/5/09 Frank Dep. at 195 (Ex. 8).)

C. Dr. Molgaard

Unable to rely on Dr. Whitehouse or Dr. Frank to advance their theories and reading the writing on the wall, the Libby Claimants turned to an epidemiologist at the University of Montana, Dr. Craig Molgaard, to legitimize Dr. Whitehouse's opinions. However, Dr. Molgaard only confirmed that Dr. Whitehouse's theories were completely unsupported.

The Libby Claimants asked Dr. Molgaard to respond to the criticisms of Dr. Whitehouse's "epidemiological" opinions contained in reports submitted in this case by Grace's epidemiologists. Dr. Molgaard's primary defense of Dr. Whitehouse's work was that it was an appropriate form of "descriptive" epidemiology "designed only to describe existing distribution of variables without regard to causal or other hypotheses." (6/25/09 Molgaard Dep. at 14 (Ex. 9).) Dr. Molgaard contrasted such studies with a controlled "analytical epidemiology" study, which would be required to actually test a hypothesis.

Accordingly, Dr. Molgaard confirmed what the Plan Proponents' experts had been saying all along -- i.e., that Dr. Whitehouse had performed no scientific analysis to actually support his opinions, but rather had offered only "untested hypotheses" that had not been validated or confirmed:

> Q. One hypothesis that Dr. Whitehouse has raised is that pleural disease caused by exposure to Libby asbestos is different, in terms of severity of lung function loss, than pleural disease caused by other forms of asbestos. That's a hypothesis that he has, correct?
>
> A. Correct.

Q. And neither he nor you have done the analytical epidemiological work to determine whether that hypothesis is true.

A. Correct.

Q. The -- you certainly haven't -- you certainly are not prepared to give an opinion, to a reasonable degree of certainty as a epidemiology -- as an epidemiologist, that the pleural disease caused by exposure to Libby asbestos is more severe, in terms of loss of lung function, than pleural disease caused by other forms of asbestos outside of Libby.

A. Correct.

Q. And in your view as an expert epidemiologist, none of the work done by Dr. Whitehouse or Dr. Frank, or any other expert in this case, would allow you to prove that hypothesis.

A. Not that I'm aware of.

(6/25/09 Molgaard Dep. at 182-83 (Ex. 9).)

Q. One hypothesis that one could test is whether or not pleural disease caused by exposure to Libby asbestos is more likely to lead to death than pleural disease caused by exposure to other types of asbestos, correct?

A. Correct.

Q. And neither you nor Dr. Whitehouse nor anybody else have done the analytical epidemiological work to prove where or not that hypothesis is true, correct?

A. Correct.

Q. So you couldn't say, for example, that someone who has pleural disease caused by exposure to Libby asbestos is more likely to die than someone who has pleural disease caused by some other asbestos, right? You couldn't say that, as a matter of epidemiological science.

A. I could not.

(*Id.* at 180-81.)

Q. And from a toxicologically, epidemiologically, everything we know in science, there's no reason to think that the stuff -- if you're exposed to the same basic stuff in Boston as you're exposed to in Libby, the disease that you ultimately get is going to be the same disease, correct?

> A. Right. The only thing, it might be -- the progression has spread. Might be -- could possibly be faster in Libby if there's a more concentrated exposure.
>
> Q. Right, that's a hypothesis that you would agree hasn't been tested.
>
> A. Right.

(*Id.* at 98-99; *see also id.* at 168-71, 180-83.)

> Q. Another hypothesis that one could have is that exposure to Libby asbestos is more likely to cause pleural disease than is exposure to chrysotile asbestos.
>
> A. Correct.
>
> Q. And neither you nor Dr. Whitehouse, nor anybody else has done the analytical epidemiological work to prove the validity of that hypothesis, correct?
>
> A. Correct.

(*Id.* at 169-71.)

Dr. Molgaard's candid admissions revealed that, despite their best efforts, the Libby Claimants had a problem that they could not fix -- they had no controlled epidemiology to support their radical hypotheses about asbestos disease in Libby.

D. Dr. Spear

The Libby Claimants' theories were further undercut by their final expert, Dr. Spear, an industrial hygienist. Many of Dr. Spear's opinions and allegations simply are not relevant, as discussed below, and not based on any reliable methodology. But the overarching importance of his testimony is that he actually blurred the bright-line distinction that the Libby Claimants attempt to assert between vermiculate exposures inside and outside of Libby. Dr. Spear testified that vermiculite from Libby -- specifically the unexpanded vermiculite with a higher asbestos content than the final expanded vermiculte products -- was shipped all around the country to expanding plants in cities from coast to coast. (7/29/09 Spear Dep. at 157-58 (Ex. 10).) Dr. Spear's testimony made clear that there are individuals outside Libby that also have exposure to Libby asbestos -- that exposure and any consequences are not unique to Libby.

ARGUMENT

The test for admissibility of expert testimony under Rule 702 is an "exacting" one. *Weisgram v. Marley Co.*, 528 U.S. 440, 442 (2000). The Supreme Court has made clear that federal trial courts must serve as "gatekeepers" to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993). The proponent of the expert testimony bears the burden of showing by a preponderance of the evidence that proffered expert testimony is both relevant and reliable. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145-46 (3d Cir. 2000); *In re W.R. Grace & Co.*, 355 B.R. 462, 471-72 (Bankr. D. Del. 2006).

Rule 702 provides that expert testimony must "assist the trier of fact . . . to determine a fact in issue." Fed. R. Evid. 702. To meet this threshold test of relevance, an expert's opinions must "speak[] clearly and directly to an issue in dispute in the case." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1321 n.17 (9th Cir. 1995). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591. Such testimony must be excluded under Rule 702 because it fails to meet a basic "precondition to admissibility." *See Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (internal quotation and citation omitted).

Rule 702 also imposes stringent requirements to ensure the reliability of proffered expert opinions. To be reliable, an expert's opinion must have "good grounds" and cannot be based on "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590; *see also In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999). Moreover, the expert's opinions must be "the product of reliable principles and methods" that are "reliably" applied "to the facts of the case." Fed. R. Evid. 702 & Advisory Committee Note (2000); *Daubert*, 509 U.S. at 590; *Oddi*, 234 F.3d at 156.

An expert's opinions must be "derived by the scientific method" and "supported by appropriate validation." *Daubert*, 509 U.S. at 590. An expert's "bald assurance of validity is not enough." *Daubert*, 43 F.3d at 1316. Even "[a] supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant." *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999).

Finally, this test must be applied at each step leading to an expert's opinion: "[A]ny step that renders the [expert's] analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994) (emphasis removed). Each of claimants' experts fails to meet these requirements.

I. DR. WHITEHOUSE'S OPINIONS SHOULD BE EXCLUDED.

The Libby Claimants' principal expert is Dr. Alan Whitehouse. In support of his opinions, he relied upon medical records for 1,800 of his patients from Libby, Montana, studies that he has performed on that population, and his general experience at Libby. As the Court is well aware, it already has ruled that Dr. Whitehouse cannot testify to any opinions based upon materials that have not been produced. The Plan Proponents will be filing shortly their motion to strike all of Whitehouse's testimony because the data underlying these opinions have not been produced. The following analysis seeks the same result based upon an independent ground: *Daubert* and Rule 702 of the Federal Rules of Civil Procedure.

A. Dr. Whitehouse has not addressed the only relevant issue here: alleged discrimination.

As a threshold matter, Dr. Whitehouse has utterly failed to address the actual issue to be decided by the Court. *See Daubert*, 509 U.S. at 591. As the Court is aware, the Libby Claimants assert that the Plan subjects them to discriminatory treatment. (*See* Libby Tr. Br. at 27-45.)

Under the Bankruptcy Code, the Plan must provide equal treatment to similarly situated claimants. *See* 11 U.S.C. §§ 524(g), 1123(a)(4); *Begier v. IRS*, 496 U.S. 53, 58 (1990). The Libby Claimants allege that the TDP criteria have an unfair or biased effect on them by failing to award them compensation in circumstances in which other claimants would receive compensation. However, they completely fail to supply any expert opinion or analysis that supports this contention.

Because Dr. Whitehouse has no opinion regarding the values of claims, his testimony could only address a contention of discrimination in process, specifically the process through which the Trust will determine how claims are compensated. As discussed in detail in the Plan Proponents' Trial Brief regarding the Libby Claimants' objections, the Trust's mechanism for compensating individual asbestos personal injury claimants is transparent and based on a quarter century of precedent. (*See* Aug. 7, 2009 Plan Proponents' Phase II Trial Brief in Response to Confirmation Objections of the Libby Claimants (Docket No. 22731) at 5-10.) To liquidate the great majority of claims, the Grace TDP, like all others, provides for an "Expedited Review" process that identifies eight asbestos-related disease levels and provides medical and exposure criteria for each disease level. If a claimant satisfies the medical and exposure criteria for a particular disease level, the claimant will, in effect, receive an "automatic settlement offer" under the TDP to pay the scheduled value for that disease level, multiplied by the payment percentage. (*See* TDP §§ 2.2 & 5.3(a).) The disease levels and their medical and exposure criteria have been developed over a long period of time to reflect, as best as can be done, existing medical science and knowledge about exposure requirements and relevant tort system considerations so that the Trust can be reasonably certain that if the Expedited Review criteria are met, the claimant in fact

has an asbestos-related disease caused by exposure to the Debtor's asbestos such that a settlement offer is warranted. (*See id.*)

Of course, it was recognized from the outset that while an Expedited Review process might satisfy the overwhelming majority of the claimants, there would be some who would not be so satisfied and, because the injunction channeled all claims against the debtor to the 524(g) trust, the trust had to have a process for dealing with the exceptions. Accordingly, there is an Individual Review process, which provides for mediation, arbitration, and even litigation to liquidate the claims where resolution is not reached amicably with the trust.

The purpose of the TDP is to establish quick compensation for clear, objectively supportable cases of severe disease. The Libby Claimants do not dispute this. The issue of discrimination, to the extent that an issue of discrimination exists, involves whether the TDP will treat non-Libby Claimants differently than Libby Claimants. At his deposition, Dr. Whitehouse made a stunning, dispositive admission demonstrating that he cannot answer that question. He admits that he has only studied Libby Claimants. He has *not* studied the non-Libby claimants:

> Q. .... Is it accurate that you've not done any scientific analysis of diffuse pleural thickening in any patient population outside of Libby?
>
> A. That is true.

(6/16/09 Dr. Whitehouse Dep. at 115 (Ex. 7).)[1]

Thus, as described below, neither he nor the Libby Claimants are able to demonstrate that the TDP does in fact treat non-Libby Claimants differently than Libby Claimants. To the contrary, by their own admissions, it does not.

1. *Dr. Whitehouse Acknowledges That the TDP Category for Severe Pleural Disease was Based Upon and Reflects Established Medical Science Regarding the Diagnosis of Severe Pleural Disease.*

[1] Diffuse pleural thickening is the only disease category where the Libby Claimants allege discriminatory treatment.

As discussed in greater detail in § I.B.3 below, the TDP criteria for severe pleural disease are based on medical criteria that are consistent with established medical science and consistent with standards promulgated by authoritative bodies such as the International Labour Organization (ILO) and the American Thoracic Society. (*See* ILO, *Guidelines for the Use of the ILO Int'l Classification of Radiographs of Pneumoconioses*, O.S.H. No. 22 (rev. ed. 2000) at 7-8 (Ex. 11); ATS, *Diagnosis and Initial Management of Nonmalignant Diseases Related to Asbestos*, 170 Am. J. Respir. Crit. Care Med. 691, 707 (2004) (Ex. 12).) In fact, at his deposition, Dr. Whitehouse acknowledged that the criteria in the TDP reflect the criteria for evaluating disease established by the medical community.

> Q. I'm asking you the same kinds of questions that I asked you about when it comes to severe asbestosis, that is, the tests that are imposed by the TDP for severe disabling pleural disease, for the diagnosis of it, those are tests that science says if they're satisfied, the claimant will be a pretty clear case of having severe disabling pleural disease, correct?
>
> A. Yes
>
> ….
>
> Q. . . . . I'm saying again, just like I did with severe asbestosis, that science says with -- where these tests, in fact, are met, people who satisfy those tests are highly likely -- are clear cases where they have severe disabling pleural disease. Not saying they're the only ones, but once they meet the tests are going to be pretty clear cases under the science; is that fair?
>
> A. Okay.
>
> Q. Is that -- I don't want an okay. Is that right?
>
> A. Yes.

(6/16/09 Dr. Whitehouse Dep. at 180-81 (Ex. 7).)

2. *Whitehouse Acknowledges That the TDP as Structured Will Capture and Compensate Cases of Serious Pleural Disease Both Inside and Outside of Libby.*

Dr. Whitehouse also acknowledges that the TDP, in its application, will effectively capture those cases inside Libby where there is severe pleural disease and will capture those cases outside of Libby where there is severe pleural disease.

> Q. Okay. Now, we also know as we went through with severe asbestosis that the test for severe disabling pleural disease level 4-B will, in fact, exclude people outside of Libby who some might say -- doctors might say, in fact, have severe disabling pleural disease, right?
>
> A. Yes.
>
> Q. And it will also exclude people within Libby who you would say have severe disabling pleural disease, correct?
>
> A. Yes.

(6/16/09 Dr. Whitehouse Dep. at 181-82 (Ex. 7).)

3. *Whitehouse has Done No Scientific Analysis Comparing the Effect of the TDP on People Inside Versus Outside of Libby.*

Dr. Whitehouse further concedes that he has not conducted any analysis that would allow him to compare how the TDP would impact claims for severe pleural disease inside and outside of Libby. While he claims to know "what happens to people in Libby, what happens to their pulmonary function relative to diffuse pleural thickening," Dr. Whitehouse admits that he has no knowledge of "what happens in the chrysotile world in that regard." (6/16/09 Whitehouse Dep. at 129 (Ex. 7).) Indeed, claimants' expert Dr. Frank testified at his deposition that *none* of the Libby Claimants' experts had done *any* analysis that would show that the TDP criteria "have any kind of disproportionate effect on people with diffuse pleural disease at Libby":

> Q. And have you done the analysis about whether the TDP category Roman IV B would have any kind of disproportionate effect on people with diffuse pleural disease at Libby?

A. I have not done that kind of analysis.

Q. Are you aware of anybody who has?

A. No.

(6/5/09 Frank Dep. at 195 (Ex. 8); *see also* 6/16/09 Whitehouse Dep. at 266-69 (Ex. 7).) Indeed, he acknowledged that "[a]nything we're going to talk about with regard to criteria probably are not going to be different for who it is. I mean, if you're talking about the science, it's the same science." (6/5/09 Frank Dep. at 78 (Ex. 8).)

So what would a comparison of how the TDP treats Libby Claimants versus other non-Libby Claimants reveal? Dr. Whitehouse does not know and cannot say.[2] Indeed, Dr. Whitehouse has even walked away from his long-expressed opinions and now acknowledges that the asbestos-related pleural disease afflicting some of the Libby Claimants is the same as the asbestos-related pleural disease found outside of Libby. (6/16/09 Whitehouse Dep. at 203 (Ex. 7) ("Well, I would agree that it's basically the same disease that been occasionally seen in chrysotile, . . .").) In the end then, on the only relevant issue -- do the TDP criteria impact the Libby Claimants differently than the non-Libby Claimants -- the Libby Claimants' experts offer no opinion.

[2] None of Dr. Whitehouse's criticisms of the TDP go to the issue of discrimination. For example, while Dr. Whitehouse criticizes the 3mm thickness requirement, he concedes that he has not compared the thickness of fibrotic pleura in Libby to the thickness of fibrotic pleura outside of Libby to determine whether people exposed to non-Libby asbestos experience severe impairment with thin levels of pleural fibrosis. (6/16/09 Whitehouse Dep. at 267-68 (Ex. 7).) Likewise, while he criticizes the blunting requirement, he acknowledges that individuals exposed to non-Libby asbestos develop severe diffuse pleural thickening without blunting of the costophrenic angle at a comparable rate to Libby Claimants. (6/16/09 Whitehouse Dep. at 62, 275 (Ex. 7).) Dr. Whitehouse also concedes that his criticism of the FEV1/FVC ratio is a "general criticism" and is not Libby-specific. (3/19/09 Whitehouse Dep. at 55-56 (Ex. 6).) Dr. Whitehouse testified that this objection is "universal across anybody exposed to asbestos" and that "any competent chest physician" would object to the use of this FEV1/FVC ratio for evaluating claimants, inside or outside of Libby. (3/19/09 Whitehouse Dep. at 35-36, 55-56 (Ex. 6).) Finally, while he argues that the TDP should permit a claimant to establish impairment based on a decrement in DLCO alone, he acknowledges that both Libby and non-Libby claimants may develop asbestos-related pleural disease that causes a decline in DLCO without a corresponding decline in FVC or TLC. (3/19/09 Whitehouse Dep. at 54 (Ex. 6).)

B. Dr. Whitehouse's criticisms are unsupported and fail to deploy any reliable methodology

Dr. Whitehouse's opinions -- which are not relevant to the issues before the Court -- also do not meet the reliability requirements established by *Daubert* and should thus be excluded. *See* Fed. R. Evid. 702 & Advisory Committee Note (2000) (expert testimony must be "the product of reliable principles and methods" that are "reliably" applied "to the facts of the case"); *Daubert*, 509 U.S. at 590 (expert's opinion must be "supported by appropriate validation"). First, another federal court already found that Dr. Whitehouse is unqualified to render epidemiological opinions about populations of individuals. Second, Dr. Whitehouse's analyses of sub-groups of his self-selected patient population are not based on any reliable epidemiological principles or methodology. Finally, Dr. Whitehouse's criticisms of the TDP criteria are unsupported and unreliable.

1. *Dr. Whitehouse is Not an Epidemiologist and is Not Qualified to Offer Opinions Regarding Groups of People.*

Opinions about patterns of disease within populations fall squarely within the expertise of an epidemiologist. Dr. Whitehouse, a treating physician with no formal training in epidemiology, seeks to offer opinions about the Libby Claimants as a group and whether, as a group, they present with a distinct medical condition.[3] As such, his opinions are fundamentally

[3] Dr. Whitehouse also offers an opinion suggesting that asbestos in Libby vermiculite is highly toxic and more toxic than other forms of asbestos. (*See* 3/19/09 Dr. Whitehouse Dep. at 21-23 (Ex. 6).) At times though, it is difficult to determine what the Libby Claimants contend with respect to the "toxicity" of asbestos in Libby vermiculite in light of changing opinions of their experts. (Compare *id.* to 12/23/08 Frank Report at 10-11 (Ex. 1).) But this is of no matter because the Court should exclude all opinions from any expert on the issue of toxicity because it bears no relevance on any confirmation issue. Toxicity of asbestos impacts the level of asbestos necessary to induce disease. The higher the toxicity, the lower the level of asbestos exposure required to cause disease. This issue would be relevant here only if the Libby Claimants were somehow claiming that the TDP's exposure requirements were too stringent and should be lower for them, as opposed to other claimants. But the Libby Claimants allege no such thing. Indeed, they do not quarrel with the exposure requirements of the TDP and assert that "Libby Claimants will have no problem meeting this criterion." (Libby Tr. Br. at 41 (Docket No. 22731).) As such, Dr. Whitehouse's contentions, and those of other experts on this issue have no relevance to these proceedings and will not assist the Court in deciding any issue in this confirmation. Because the toxicity issue has no relevance, the Plan Proponents have elected not to address the reliability problems associated with the Libby Claimants' assertions concerning

epidemiological in nature. *See In re W.R. Grace & Co.*, 355 B.R. at 482 (observing that "[e]pidemiological studies examine the incidence, distribution, and etiology of disease in human populations," citing Reference Guide on Epidemiology, in Reference Manual on Scientific Evidence 335 (2d ed. 2000)).

However, Dr. Whitehouse concedes that he is not an epidemiologist, and indeed the court in the criminal case recently held that he lacks the requisite qualifications to offer opinions in that area. (*See U.S. v. W.R. Grace*, Doc. No. 1103, Apr. 21, 2009 Order at 4 (finding that "Dr. Whitehouse does not possess specialized knowledge in the field of epidemiology[]" and "strik[ing] the inadmissible opinion"); *United States v. W.R. Grace*, Mar. 4, 2009, Tr. vol. 7 at 1692-95 (D. Mont.) (Ex. 13.) Accordingly, his opinions fail to meet a threshold requirement for admissibility under Rule 702.

2. *Dr. Whitehouse's Various Analyses of Sub-groups of his Patient Population are Not Based Upon Any Proper Epidemiological Method.*

Dr. Whitehouse purports to engage in epidemiology, but his opinions have none of the hallmarks of the established methods of the science of epidemiology. (*See* 4/6/09 Moolgavkar Report at 2 (Ex. 14).) As an example, Dr. Whitehouse's original "population" started out as 1,800 people from his medical practice whom he alleges have asbestos-related diseases. This was not a randomly selected group of people but rather a self-selected group of sick patients, many of whom were referred to Dr. Whitehouse by the lawyers in this case. When he was unable to produce the medical records for nearly half of these individuals, he simply cut his data set in half. This exclusion of half of the population in his data set was not based on any

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toxicity. In short though, they have performed absolutely no analysis on this complex scientific issue and have no basis to render any opinion on it, as confirmed by their own epidemiologist, Dr. Molgaard. (6/25/09 Molgaard Dep. at 160-61 (Ex. 9) (confirming that the Libby Claimants have not done any scientifically valid analysis to test their toxicity hypothesis).)

generally accepted epidemiological methods. Rather, it was a litigation driven decision with absolutely no basis in science. Next, Dr. Whitehouse selected 79 (now 76) people from his CARD Mortality Study, all of whom originally were chosen because they had died, and asserted that he could extrapolate medical evidence relating to those 79 individuals to the 950 Libby Claimants without making any effort to compare with any scientific rigor or established scientific method the 79 dead patients with the 950 Libby Claimants. However, he has never produced a single document explaining how such an extrapolation could be performed, much less validated. His opinion is simply impermissible *ipse dixit*. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert"); *Oddi*, 234 F.3d at 156 (upholding the exclusion of proposed expert's testimony where "[party] could not establish the existence of [expert's] methodology and research let alone the adequacy of it").

Dr. Whitehouse's utter failure to utilize established epidemiological methods in his attempts at epidemiology are further illustrated in other analyses he advances in this case. Again, none of these analyses relate to the issue of discrimination, and as such, have no relevance. But the methodological problems apparent in them are additional grounds for this exclusion.

a. *CARD Mortality Study*

One of the primary "studies" upon which Dr. Whitehouse relies to support his assertion that the Libby Claimants suffer from a different and more serious medical condition is a "mortality study" involving patients at the Center for Asbestos Related Disease (CARD). (*See* 5/16/09 Whitehouse Report ¶¶ 31-32 (Ex. 15).) However, Dr. Whitehouse completely failed to follow any reliable methodology in conducting this study:

- Dr. Whitehouse fails to provide a protocol for his study or any information about how the study was designed or how the study subjects were assembled. (*See* 4/6/09 Moolgavkar Report at 2 (Ex. 14); 4/6/09 Ory Report at 8 (Ex. 16).)

- The comparison of individuals who already have asbestos disease with an occupational cohort of asbestos workers is scientifically invalid and quite frankly makes no sense epidemiologically. (4/6/09 Moolgavkar Report at 2 (Ex. 14).) The two populations are simply not comparable. (*See id.*)

- There is no showing that the subset of Dr. Whitehouse's patient population that was selected for the CARD Mortality Study (using unknown criteria) was representative of the CARD population, much less the Libby Claimants as a whole. (6/16/09 Whitehouse Dep. at 189-90 (Ex. 7).)

- Dr. Whitehouse has absolutely no information regarding the level of exposure to Libby fiber in his patient population. Despite this, Dr. Whitehouse argues that his patients had similar mortality patterns to asbestos insulation workers "who had much higher exposures." He lacks any information to make any comparison between the exposure levels of the two populations. (*See* 4/6/09 Moolgavkar Report at 3 (Ex. 14); 4/6/09 Ory Report at 8 (Ex. 16).) *See also W.R. Grace*, 455 F. Supp. 2d at 1154 (excluding expert testimony purporting to compare asbestos-related disease in Libby workers with workers in South Carolina because expert's report "contains no data relating to the comparative exposure of the workers or the sizes and forms of the asbestos fibers to which they were exposed").

- Dr. Whitehouse used unreliable methodology in ascertaining the cause of death in his study. (10/18/07 Whitehouse Dep. at 231-32 (Ex. 17).) Claimants' own epidemiology expert, Dr. Molgaard testified that Dr. Whitehouse's approach was inappropriate: (6/25/09 Molgaard Dep. at 87-88 (Ex. 9).)

Despite these flaws, the Libby Claimants and Dr. Whitehouse continue to cite the CARD study as if its conclusions can be asserted with scientific certainty. Clearly they cannot. The Libby Claimants' own epidemiologist said just that. (6/25/09 Dr. Molgaard Dep. at 180-83 (Ex. 9).) The CARD study merely formulates a hypothesis about Dr. Whitehouse's Libby patients. It is not designed, nor is it capable of testing or confirming, the hypothesis Dr. Whitehouse takes from it. (*See id.*) Thus, it is not reliable science and should be excluded.

b. *Whitehouse Observational Study*

To support his allegation that pleural disease from Libby asbestos exposure is "highly progressive," Dr. Whitehouse also cites a 2004 observational study of lung function decrement he performed based on a sub-group of his patients exposed in the Libby area (the "Whitehouse Observational Study" or "WOS").[4] (5/16/09 Whitehouse Report ¶ 38 (Ex. 15).) However, like the CARD Mortality Study, the WOS is scientifically unreliable and suffers from a number of serious methodological flaws:

- The subjects for this study were not randomly selected from the Libby population, but rather were selected from Dr. Whitehouse's patient population, which included patients that were referred by plaintiffs' counsel, resulting in significant selection bias.[5] (*See* Moolgavkar Report at 7 (Ex. 14); Ory Report at 22-24 (Ex. 16).)[6] Dr. Whitehouse claimed in his study that these patients were "representative" of the Libby area population, but he subsequently recanted this statement. (*See* 3/19/09 Whitehouse Dep. at 196-97 (Ex. 6).) Accordingly, this study suffers from significant selection bias and cannot be generalized to the Libby population. *See In re TMI Litig.*, 193 F.3d 613, 708 (3d Cir. 1999) (excluding epidemiological study where participants in the study groups were chosen by plaintiffs' consultant and there was no attempt to insure that participants were not selected or excluded in a manner that would bias the study).

- Dr. Whitehouse acknowledges that he did not apply selection criteria designed to avoid confounding, as stated in his paper. For example, while his study claims to have excluded individuals with confounding medical conditions, such as COPD and prior thoracic surgery, during his deposition he admitted that such patients were included. (*See* 3/19/09 Whitehouse Dep. at 246-49 (Ex. 6).)

- Dr. Whitehouse failed to use a control group. (*See* 4/6/09 Moolgavkar Report at 7 (Ex. 14).) As such, his study cannot form the basis for scientifically valid

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[4] *See* Alan Whitehouse, *Asbestos-Related Pleural Disease Due to Tremolite Associated with Progressive Loss of Lung Function: Serial Observations in 123 Miners, Family Members, and Residents of Libby, Montana*, 46 Am. J. Indus. Med. 219 (2004) (Ex. 18).

[5] Dr. Whitehouse initially denied that none of the patients in this study were referred by plaintiffs' counsel, Mr. Heberling. (*See* 10/18/07 Whitehouse Dep. at 203 (Ex. 17).) However, after he was confronted with documents showing the contrary, he acknowledged that patients in his study had been referred by lawyers. (3/19/09 Whitehouse Dep. at 219 (Ex. 6).)

[6] Dr. Whitehouse does not indicate how he selected these 491 patients, but does represent in his paper that they were not among the more than 1,000 individuals who were identified by the ATSDR Screening Study as having pleural abnormalities. However, this statement in his paper is demonstrably incorrect. (*See* Ory Report at 22 (Ex. 16).)

conclusions. Without control groups, it is not possible to determine whether any loss of lung function should be attributed to the specific disease agent being studied or another cause. *See In re W.R. Grace & Co.*, 355 B.R. at 483 (citing Reference Manual on Scientific Evidence 338-47 (2d ed. 2000)); *In re Diet Drugs Prods. Liab. Litig.*, No. MDL120, 2000 WL 962545, at *6 (E.D. Pa. June 28, 2000). *See also Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151, 1161-62 (E.D. La. 1997) ("[C]ourts have frequently rejected case studies as an insufficient basis to decide causation when they lack control groups.") (citations omitted)).[7]

- Dr. Whitehouse failed to collect any information regarding exposure levels. Accordingly, he makes no attempt to relate decrements in lung function to the level of asbestos exposure in his study population. As a result, no conclusions regarding the association of asbestos exposure at Libby and loss of lung function can be drawn from this study. (*See* 4/6/09 Moolgavkar Report at 6-7 (Ex. 14).)

- Dr. Whitehouse improperly analyzed the data he did obtain. While Dr. Whitehouse contends that the annual decline in lung function in the population he studied increased by two to three percent per year on average, these findings were based on only two data points per person studied: the first and last PFT for each of the 123 subjects in the study. (*See* 3/19/09 Dr. Whitehouse Dep. at 257-58 (Ex. 6).)

These are just some of the numerous flaws in Dr. Whitehouse's studies. While "*any* step that renders the [expert's] analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible*," Dr. Whitehouse's studies are particularly unreliable because they suffer from *multiple* flaws at each stage of the analysis. *See In re Paoli*, 35 F.3d at 745 (emphasis in original). And finally, just like the CARD Study, this study at most, according to the Libby Claimants' own epidemiologist, Dr. Molgaard, is designed to assist in hypothesis formulations (descriptive epidemiology). It is not designed, nor is it even remotely capable, of testing any hypothesis. (6/25/09 Dr. Molgaard Dep. at 180-83 (Ex. 9).)

[7] In fact, Dr. Becklake, whom Dr. Whitehouse cites in the WOS, acknowledges the need for control groups when conducting a longitudinal study such as the WOS. *See* Margaret Becklake et al., *NHLBI Workshop Summary Longitudinal Analysis in Pulmonary Disease Epidemiology*, 137 Am. Rev. Respiratory Dis. 1241, 1243 (1988) ("Although in a longitudinal study each subject is supposed to serve as his or her own control, there was general agreement that a well-designed longitudinal pulmonary function study of the effects of a putative hazard must include an explicit, carefully selected control group.").

3. *Dr. Whitehouse's Particular Criticisms of the TDP are Unsupported and Unreliable.*

Dr. Whitehouse lists a variety of objections to the TDP. However, none of these objections are based on reliable methodologies. With each objection, Dr. Whitehouse acknowledges that the allegedly objectionable criterion is reasonably related to severity of disease.

a. *Blunting of the costophrenic angle*

Dr. Whitehouse claims, for example, that Libby Claimants may develop diffuse pleural thickening without blunting of the costophrenic angle and that therefore blunting should be eliminated from the TDP criteria. (5/16/09 Whitehouse Report ¶¶ 72, 75 (Ex. 15).) Blunting of the costophrenic angle is an objective x-ray finding that numerous peer reviewed studies have found is associated with loss of lung function.[8] In the wake of these studies, the International Labour Organization has determined that diffuse pleural thickening should be identified only in the presence of an associated blunted costophrenic angle. (*See* ILO, *Guidelines for the Use of the ILO Int'l Classification of Radiographs of Pneumoconioses*, O.S.H. No. 22 (rev. ed. 2000) at 7-8 (Ex. 11).) Additionally, the 2004 ATS statement specifically provides that "Diffuse pleural fibrosis extends continuously over a portion of the visceral pleura, often causing adhesions to the parietal pleura, involving the fissures and ***obliterating the costophrenic angle***."[9] Dr. Whitehouse acknowledges that blunting of the costophrenic angle has been recognized in the

[8] *See* 12/23/08 Welch Report at 16 (Ex. 19); 12/29/08 Henry Report at 10 (Ex. 20); D. Hanel et al., Imaging of Diseases of the Chest 450-61, 1056-62 (4th ed. 2005) (Ex. 21); Amiele et al., *Asbestos-Related Pleural Diseases: Dimensional Criteria Are not Appropriate to Differentiate Diffuse Pleural Thickening from Pleural Plaques*, 45 Am. J. Ind. Med. 289 (2004) (Ex. 22); R. Lilis et al., *Pulmonary Function and Pleural Fibrosis: Quantitative Relationships With an Integrative Index of Pleural Abnormalities*, 20 Am. J. Indus. Med. 145 (1991) (Ex. 23).

[9] ATS, *Diagnosis and Initial Management of Nonmalignant Diseases Related to Asbestos*, 170 Am. J. Respir. Crit. Care Med. 691, 707 (2004) (emphasis added) (Ex. 12), cited in 12/29/08 Henry Report at 8.

medical literature and by authoritative medical organizations as a marker of severity of pleural disease.

> Q. Would you, therefore, agree with me that the diffuse pleural thickening associated with blunting of the costophrenic angle has a clear track record of being associated also with very severe impairment?
>
> A. Yes.

(6/16/09 Dr. Whitehouse Dep. at 157 (Ex. 7).)

b. *Thickness of the pleural abnormality*

Dr. Whitehouse likewise alleges that Libby Claimants can exhibit severe cases of pleural disease even when they have very thin layers of fibrosis that cover only limited areas of the chest wall. (5/16/09 Whitehouse Report ¶¶ 73, 77 (Ex. 15).) Once again, the thickness of pleural fibrosis provides a reliable method for identifying actual pleural fibrosis that may be associated with diffuse pleural thickening that causes a loss of lung function. Fraser and Pare, a reference quoted by Dr. Whitehouse, describes diffuse pleural thickening as "a continuous area of pleural thickening ***greater than 3mm*** extends for more than 8 cm craniocaudally and 5 cm around the perimeter of the hemithorax."[10] Moreover, while Dr. Whitehouse asserts that the 2004 ATS guidelines provide no minimum thickness for diffuse pleural thickening, but rather simply state that it "ranges in thickness from less than 1 mm up to 1 cm or more" (5/16/09 Whitehouse Report ¶ 73 (Ex. 15)), the description in the 2004 ATS statement relates to *pathologic* specimens, which can be assessed using more sensitive measurement techniques that can detect thickening to the 1-2 mm thickness level -- *not* the chest radiographs or chest CTs that are the subject of the TDP criteria. (*See* Henry Report at 11 (Ex. 20).)

[10] R. Fraser et al., 4 *Fraser & Pare's Diagnosis of Diseases of the Chest* 2430-37 (4th ed. 1999) (emphasis added), cited in Henry Report at 11 (Ex. 24).

c. *FEV1/FVC*

Dr. Whitehouse alleges that certain Libby Claimants who have asbestos-related disease have depressed FEV1/FVC ratios that are below 65%. (5/16/09 Whitehouse Report ¶ 64 (Ex. 15).) The FEV1/FVC ratio is designed to determine whether lung function decline measured by Total Lung Capacity or Forced Vital Capacity is caused by restrictive disease (which the medical community agrees is associated with non-malignant asbestos-related diseases) or obstructive disease (which the medical community agrees generally is not). The 65% requirement for the FEV1/FVC ratio is an accepted means of determining whether the decline in lung function is restrictive in nature. (*See* 12/23/08 Welch Report at 17 (Ex. 19).) If the FEV1/FVC ratio is reduced below this figure, then it is likely that the claimant suffers from obstructive lung disease, which includes many smoking-related diseases such as emphysema and chronic obstructive pulmonary disease. (*Id.*)

d. *DLCO*

Finally, Dr. Whitehouse argues that the TDP should permit a claimant to establish impairment based on a decrement in DLCO alone, as opposed to requiring a decline in FVC and TLC. (5/16/09 Whitehouse Report ¶ 79 (Ex. 15).) As Dr. Whitehouse admitted though, there are hundreds of medical conditions that cause a decrement in DLCO, and a decreased DLCO certainly is not dispositive for identifying asbestos-related impairment. (3/19/09 Whitehouse Dep. at 52 (Ex. 6); *see also id.* at 53 ("there's a very large number of interstitial lung diseases, all of which are capable of producing a decrease in DLCO"), 262.) Accordingly, precluding a claimant from establishing impairment based on a decline in DLCO alone is reasonable.

4. *The Testimony of the Libby Claimants' Own Experts Confirms That Dr. Whitehouse's Opinions Are Completely Unsupported And Unreliable.*

At bottom, none of the opinions Dr. Whitehouse offers are based on reliable scientific methodologies. As claimants' own epidemiologist Dr. Molgaard testified, Dr. Whitehouse's opinions constitute nothing more than a series of untested "hypotheses":

> Q. One hypothesis that Dr. Whitehouse has raised is that pleural disease caused by exposure to Libby asbestos is different, in terms of severity of lung function loss, than pleural disease caused by other forms of asbestos. That's a hypothesis that he has, correct?
>
> A. Correct.
>
> Q. And neither he nor you have done the analytical epidemiological work to determine whether that hypothesis is true.
>
> A. Correct.
>
> Q. The -- you certainly haven't -- you certainly are not prepared to give an opinion, to a reasonable degree of certainty as a epidemiology -- as an epidemiologist, that the pleural disease caused by exposure to Libby asbestos is more severe, in terms of loss of lung function, than pleural disease caused by other forms of asbestos outside of Libby.
>
> A. Correct.
>
> Q. And in your view as an expert epidemiologist, none of the work done by Dr. Whitehouse or Dr. Frank, or any other expert in this case, would allow you to prove that hypothesis.
>
> A. Not that I'm aware of.

(6/25/09 Molgaard Dep. at 182-83 (Ex. 9).)

> Q. One hypothesis that one could test is whether or not pleural disease caused by exposure to Libby asbestos is more likely to lead to death than pleural disease caused by exposure to other types of asbestos, correct?
>
> A. Correct.
>
> Q. And neither you nor Dr. Whitehouse nor anybody else have done the analytical epidemiological work to prove where or not that hypothesis is true, correct?
>
> A. Correct.

> Q. So you couldn't say, for example, that someone who has pleural disease caused by exposure to Libby asbestos is more likely to die than someone who has pleural disease caused by some other asbestos, right? You couldn't say that, as a matter of epidemiological science.
>
> A. I could not.

(*Id.* at 180-81.)

> Q. And from a toxicologically, epidemiologically, everything we know in science, there's no reason to think that the stuff -- if you're exposed to the same basic stuff in Boston as you're exposed to in Libby, the disease that you ultimately get is going to be the same disease, correct?
>
> A. Right. The only thing, it might be -- the progression has spread. Might be -- could possibly be faster in Libby if there's a more concentrated exposure.
>
> Q. Right, that's a hypothesis that you would agree hasn't been tested.
>
> A. Right.

(*Id.* at 98-99; *see also id.* at 168-71, 180-83.)

The Federal Rules make clear that such testimony must be excluded as unreliable. To be reliable, an expert's opinion must have "good grounds" and be "supported by appropriate validation." *Daubert*, 509 U.S. at 590. An expert's testimony cannot be based on "subjective belief or unsupported speculation." *Id.* Accordingly, "it is the proponent of the theory that must test the hypothesis to affirm its reliability." *Bauer v. Bayer A.G.*, 564 F. Supp. 2d 365, 380 (M.D. Pa. 2008) (citing *Paoli*, 35 F.3d at 742). "Where, as here, an expert's hypothesis is confirmed neither by scientific literature nor by proper testing, the expert's proffered testimony remains 'speculative and unreliable.'" *Id.* (quoting *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 322 (3d Cir. 2003)). "[M]ere hypotheses" are "inadmissible as a matter of law under … *Daubert*." *See Curtis v. Besam Group*, No. 05-CV-2807(DMC), 2008 WL 1732956, at *4 (D.N.J. Apr. 10, 2008).[11]

[11] *See also, e.g., In re Propulsid Products Liab. Litig.*, 261 F. Supp. 2d 603, 615 (E.D. La. 2003) (expert opinions excluded because they were "[a]t best … untested hypotheses"); *Kirstein v. W.M. Barr & Co., Inc.*, 983 F. Supp.

C. Dr. Whitehouse cannot offer relevant and reliable testimony as a treating physician.

As a treating physician, Dr. Whitehouse can only testify about diagnoses of individual patients. Any attempt to address issues other than the actual diagnoses and offer opinions about the population as a whole would go beyond his area of expertise given his lack of qualifications to offer epidemiological opinions. These individual diagnoses, however, are irrelevant to the Libby Claimants' objections. As the Court has previously observed, it is not "appropriate for this Court to be doing mini-trials on personal injury actions." (5/14/09 Tr. at 71.) "That's not the plan confirmation function." (*Id.*) A diagnosis of an individual in Libby does not bear upon the issue of discrimination. An individual diagnosis, even a collection of diagnoses of Libby Claimants, does not relate at all to non-Libby claimants and cannot bear on a comparison of how the TDP impacts people in Libby as opposed to outside of Libby.

Moreover, while claimants concede that the Court's prior ruling would "strike his testimony as to virtually everything" (7/27/09 Tr. at 156), allowing Dr. Whitehouse to testify as a fact witness will only invite the Libby Claimants to attempt to circumvent this Court's ruling by introducing his excluded expert testimony in the guise of fact witness testimony. Rule 701 clearly prohibits such an outcome. Under the rule, lay witnesses may not provide testimony that requires "scientific, technical, or other specialized knowledge within the scope of Rule 702." *See* Fed. R. Evid. 701. This language was included in the rule to ensure that "a party will not evade the expert witness disclosure requirements set forth in Fed. R. Civ. P. 26 and Fed. R. Crim. P. 16 by simply calling an expert witness in the guise of a layperson." *See id.* Advisory Committee Comment (2000). *See also Rodriguez v. Town of West New York*, 191 Fed. Appx.

753, 759 (N.D. Ill. 1997) (expert's testimony excluded where expert offered "only an untested hypothesis"); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1234 (D. Colo. 1998) (expert testimony excluded because it was "at best an untested hypothesis").

166, 169 (3d Cir. 2006) (affirming exclusion of opinion testimony by physician who failed to comply with Fed. R. Civ. P. 26); *Collins v. Prudential Inv. and Retirement Services,* 119 Fed. Appx. 371, 379 (3d Cir. 2005) (same); *Lamere v. N.Y. State Office for the Aging*, 223 F.R.D. 85, 89-90 n.4 (N.D.N.Y. 2004) (treating physician is limited to the "four corners" of medical records if fails to comply with Fed. R. Civ. P. 26).

In sum, it is not relevant whether Dr. Whitehouse believes that the TDP's criteria for Expedited Review should compensate all of the truly sick people in Libby. That is not the purpose of the TDP; rather the TDP aims to provide immediate compensation to clear cases of disease with objective findings that demonstrate that an individual truly has disease. If the TDP had to compensate every person with severe pleural disease, regardless of whether they meet objective medical criteria, that would undermine the entire purpose of the TDP and render it useless. Moreover, any opinion by Dr. Whitehouse about an individual diagnosis and whether that person is compensated under the TDP's Expedited Review procedure is irrelevant to the issue of discrimination because it does not bear on whether people in Libby are treated differently than people outside of Libby.

II. OTHER LIBBY EXPERTS' OPINIONS SHOULD BE EXCLUDED.

In an attempt to salvage and legitimize Dr. Whitehouse's opinions, the Libby Claimants have designated several additional experts. However, each of these experts acknowledge that their opinions do not address the only relevant issue here: whether the TDP criteria discriminate against the Libby Claimants. Moreover, each of them rely on Dr. Whitehouse's completely unsupported and unreliable analysis of his self-selected patient population -- i.e., "the heart of [claimants'] case in these confirmation proceedings." (*See* 7/27/09 Tr. at 160.) Accordingly, their opinions likewise should be excluded.

A. Dr. Frank

The Libby Claimants have identified a second medical expert, Dr. Arthur Frank. Dr. Frank is an occupational medicine physician based in Philadelphia, Pennsylvania who has been an active participant in asbestos litigation over the years, having been deposed over a thousand times. (6/5/09 Frank Dep. at 113-14 (Ex. 8).) In his expert report, Dr. Frank agreed based on Dr. Whitehouse's work that "there appears to be" more progression of disease in the Libby population (Frank Report ¶ 19 (Ex. 1)) and a greater "disease severity" (*id.* ¶ 24). However, like those of Dr. Whitehouse, his opinions are completely irrelevant and unreliable.

1. Dr. Frank acknowledges that neither he nor any of the Libby Claimants' other experts has addressed the only relevant issue here: alleged discrimination.

Dr. Frank concedes that his opinions have absolutely no relevance to the issue the Court must address here -- alleged discrimination against the Libby Claimants. Indeed, Dr. Frank concedes that *no one* has done *any* analysis that would show that the TDP criteria "have any kind of disproportionate effect on people with diffuse pleural disease at Libby."

> Q. And have you done the analysis about whether the TDP category Roman IV B would have any kind of disproportionate effect on people with diffuse pleural disease at Libby?
>
> A. I have not done that kind of analysis.
>
> Q. Are you aware of anybody who has?
>
> A. No.

(6/5/09 Frank Dep. at 195 (Ex. 8).)

Moreover, he *concedes* that the Libby Claimants have the exact same diseases as those suffered by other claimants:

> Q. Well, the diseases that people in Libby suffer are no different than the diseases people outside of Libby suffer, is that correct?

A. It's the same set of asbestos-related diseases.

(*Id.* at 195.) His opinions simply have nothing to do with any alleged discrimination under the TDP.

2. Dr. Frank's criticisms are unsupported and unreliable.

To the extent Dr. Frank offers criticisms, they are not based on reliable science. Not only does Dr. Frank "rely upon and concur in" Dr. Whitehouse's analysis, but he has jointly submitted various expert reports written by Dr. Whitehouse and Libby Claimants' counsel. (*See* 12/23/08 Frank Report at 12 (Ex. 1).) Dr. Frank's original confirmation report specifically relies upon the opinions expressed in Dr. Whitehouse's December 2008 Report. (*Id.*) In addition, Dr. Frank and Whitehouse issued a series of rebuttal reports authored by claimants' counsel and signed by both men. (*See, e.g.*, 5/15/09 Response of Dr. Frank and Dr. Whitehouse to Grace's Dr. J. Parker Report, 4/6/09 (Ex. 25); 5/15/09 Response of Dr. Frank and Dr. Whitehouse to Grace's Dr. D. Weill Report, 4/6/09 (Ex. 26); 5/15/09 Response of Dr. Frank and Dr. Whitehouse to Report of the ACC's Dr. L. Welch, March 2009 (Ex. 27).) Thus, for example, Dr. Frank acknowledged during his deposition that he relied upon the CARD Mortality Study, Whitehouse observational study, and Dr. Whitehouse's clinical findings in reaching the opinions he seeks to offer in this case. (6/5/09 Frank Dep. at 46, 85, 213-16 (Ex. 8).) Accordingly, his opinions suffer from the exact same defects that render Dr. Whitehouse's opinions inadmissible under *Daubert*. *See, e.g.*, *Adams v. Cooper Indus., Inc.*, No. 03-476-JBC, 2007 WL 2219212, at *6 (E.D. Ky. July 30, 2007) (excluding expert's opinion that relied upon another expert's opinion that had previously been excluded); *Autoforge, Inc. v. American Axle & Mfg., Inc.*, No. 02-01265, 2008 WL 65603,

at *11 (W.D. Pa. Jan. 4, 2008) (excluding lay witness testimony because it relied on previously excluded expert report).[12]

B. Dr. Molgaard's opinions should be excluded.

The Libby Claimants also intend to offer expert testimony from Dr. Craig Molgaard, an epidemiologist at the University of Montana, who was brought in to legitimize Dr. Whitehouse's "epidemiological" opinions. (*See* 5/18/09 Molgaard Report ¶¶ 4-7 (Ex. 2).) However, Dr. Molgaard does not purport to offer any opinions regarding alleged discrimination. Moreover, his analysis merely confirms that Dr. Whitehouse has offered at best untested "hypotheses" that fail to meet the requirements of Rule 702 and *Daubert*.

1. Dr. Molgaard's opinions do not purport to address the issue of discrimination.

As a threshold matter, Dr. Molgaard does not even purport to offer any opinions regarding alleged discrimination. To the contrary, the bulk of his opinions seek to legitimize Dr. Whitehouse's flawed studies. Dr. Whitehouse, in turn, has conceded that he has done no analysis that addresses whether the TDP criteria discriminate against the Libby Claimants. (6/16/09 Whitehouse Dep. at 145, 129 (Ex. 7).) Accordingly, Dr. Molgaard's testimony is simply irrelevant to the only issue that will be addressed in the confirmation proceedings.

[12] Dr. Frank lacks the requisite knowledge of the literature to offer expert opinions about pleural disease in Libby in the first place. During his deposition, Dr. Frank candidly acknowledged that he was not familiar with the epidemiological literature regarding diffuse pleural thickening and associated pulmonary impairment. (6/5/09 Frank Dep. at 151, 160-61 (Ex. 8).) Without even a cursory understanding of the relevant literature, Dr. Frank cannot offer an expert opinion about the specific disease at issue here. Indeed, during Dr. Frank's deposition it became apparent that he may not have even read his own expert reports. For example, Dr. Frank was not familiar with the term "confluent plaques" (6/5/09 Frank Dep. at 159 (Ex. 8)), yet that same term is used repeatedly throughout Dr. Frank's joint rebuttal reports (*see, e.g.*,5/15/09 Response of Dr. Frank and Dr. Whitehouse to Report of the ACC's Dr. L. Welch, March 2009, at 10 (Ex. 27)). Likewise, Dr. Frank's joint reports cite McCloud (1985), but Dr. Frank acknowledged that he had ultimately not reviewed this and other studies relevant to defining diffuse pleural thickening. (*See* 6/5/09 Frank Dep. at 163-67, 171 (Ex. 8).) Dr. Frank's lack of familiarity with critical portions of his own report calls into question the reliability of any testimony he may offer at the confirmation hearing. *See Callaway Golf Co. v. Acushnet Co.*, No. 06-91-SLR, 2007 WL 4165401, at *1 (D. Del. Nov. 20, 2007) (finding that the expert's report "reflect[ed] no personal knowledge of any material aspect of the subject matter").

2. Dr. Molgaard confirms that Dr. Whitehouse offers only untested "hypotheses", which are inadmissible under Rule 702 and *Daubert*.

Moreover, while Dr. Molgaard was brought in to legitimize Dr. Whitehouse's opinions, he actually demonstrates that they are inadmissible. In his report, Dr. Molgaard states that Dr. Whitehouse's studies represent examples of "descriptive epidemiology," which he defines as "a study concerned with and designed only to describe existing distribution of variables without regard to causal or other hypotheses." (6/25/09 Molgaard Dep. at 14 (Ex. 9).) He contrasts such studies with "analytical epidemiology," which involves studies that are actually designed to test a hypothesis. Because Dr. Whitehouse's work is merely descriptive in nature, Dr. Molgaard acknowledges that it simply formulates inadmissible "hypotheses". (*See* 6/25/09 Molgaard Dep. at 169-83 (Ex. 9).) *See Pride v. BIC Corp*, 218 F.3d 566, 578 (6th Cir. 2000) (excluding expert testimony under *Daubert* where experts failed "to test their hypotheses in a timely and reliable manner or to validate their hypotheses by reference to generally accepted scientific principles . . . .").

Nor does Dr. Molgaard supply the missing analysis. While Dr. Molgaard suggests in his supplemental report that various studies, such as Peipens (2003), can be "combined with other studies in the conceptual model known as Ecoepidemiology to assess etiological events in Libby," (7/07/09 Molgaard Report at 2 (Ex. 28)), during his deposition Dr. Molgaard conceded that "ecoepidemiology" is just another form of "descriptive epidemiology" and is "not considered a tremendously strong research design." (6/25/09 Molgaard Dep. at 155-57 (Ex. 9).) And to be sure, throughout his deposition, Dr. Molgaard is clear: all forms of descriptive epidemiology are designed to formulate hypotheses, not test them.

To the extent Dr. Molgaard attempts to rebut some of the other criticisms of Dr. Whitehouse's work, his opinions are unreliable. As he acknowledged during his deposition, his

opinions depend upon certain assumptions that are demonstrably false. For example, in responding to certain criticisms of Dr. Whitehouse's CARD Mortality Study, Dr. Molgaard simply "assume[d] that Dr. Whitehouse's diagnoses of asbestos related disease in his patient population and his best evidence judgments in the CARD Mortality Study are accurate." (6/25/09 Molgaard Dep. at 92 (Ex. 9).) He was not asked to make any independent effort to validate or verify the reliability of the diagnoses or best evidence judgments used in the study. But, when Dr. Molgaard was informed that Dr. Whitehouse had not used available autopsy information in ascertaining the cause of death in the CARD Mortality Study, Dr. Molgaard disagreed with Dr. Whitehouse's methodology: "As an epidemiologist, I would think that he should have relied on the autopsy pathology." (6/25/09 Molgaard Dep. at 87-88.)

But the heart of the problem with Dr. Molgaard's analysis in this case is the fact that he does not have one. He was brought into this case by the Libby Claimants to be their epidemiologist -- but he does not analyze any data. More importantly, he provides no method by which to judge what he did do, which was to review Dr. Whitehouse's various analyses. He does not indicate what standard he used. And most importantly, he did not critically test any of Dr. Whitehouse's hypotheses, or even any of his assumptions. As such, he offers no opinion that would be helpful to the Court, based on any reliable scientific method.

C. Dr. Spear's opinions should be excluded.

The Libby Claimants' final expert, Dr. Spear, is an industrial hygienist from Butte, Montana who seeks to offer testimony regarding Grace's historical conduct. While many of his opinions and allegations are not relevant and are outside the scope of his expertise, significantly Dr. Spears testified that vermiculite exposures occurred both inside and outside of Libby.

1. Dr. Spears' testimony confirms that vermiculite exposures occurred inside and outside of Libby.

During his deposition, Dr. Spear testified that vermiculite from Libby -- specifically the unexpanded vermiculite with a higher asbestos content than the final expanded vermiculte products -- was shipped all around the country to expanding plants in cities from coast to coast.

> Q. Okay. And part of the Libby operation involved sending ore elsewhere, correct?
>
> A. Yes.
>
> Q. Okay. And this was unexpanded vermiculite, correct?
>
> A. Yes.
>
> Q. And was there asbestos in that vermiculite?
>
> A. Yes.
>
> Q. And that asbestos would go where -- or, excuse me, that vermiculite would go where?
>
> A. Well, the vermiculite would go to expanding plants across the country.

(Spears Dep. at 157 (Ex. 10); *see also id*. at 158.)

Dr. Spear's testimony made clear that there are individuals outside Libby who also have exposure to Libby asbestos -- i.e., that exposure and any consequences are not unique to Libby:

> Q. Have you studied exposures to asbestos from Libby that occurred outside of Libby?
>
> A. We have done some preliminary work in Spokane.
>
> Q. What kind of work is this?
>
> A. It was, again, through the COBRE grant. And we basically did a very preliminary survey of neighborhoods surrounding the Spokane expanding plant.
>
> Q. And what were the findings of that analysis?
>
> A. Well, they're preliminary. In fact, they're still being worked up but -- so it's, I mean we -- fibers were detected in areas outside of the plant that is no longer there.

> Q. Okay. So this is just one example; however, in this example, it illustrates that people outside of an expanding plant outside of Libby -- in this case, Spokane -- may have been exposed to asbestos that was released during the expanding process, correct?
>
> A. I suppose that's correct.

(*Id.* at 159-60.)

2. Dr. Spear's allegations regarding' Grace's historical conduct and other opinions are irrelevant to the confirmation proceedings.

Dr. Spear's remaining opinions are irrelevant to the confirmation proceedings. The bulk of his opinions concern Grace's historical conduct. (*See* 7/29/09 Spear Dep. at 99-114 (Ex. 10).) Specifically, he alleges that Grace did not adhere to the prevailing industrial hygiene standards at various times during its operation of the Libby vermiculite mine and mill, resulting in the exposure of the Libby population.

However, Grace has not denied that historical conditions at the Libby mine and mill created occupational conditions that could and did cause disease. This is not in dispute. Moreover, whether or not Grace violated industrial hygiene standards is completely irrelevant to the Libby Claimants' assertion that they suffer unequal treatment under the disease criteria contained in the TDP.

Dr. Spear also intends to discuss a study he performed that found asbestos imbedded in tree bark at Libby. According to Dr. Spear, his study "supports the scientific hypothesis that asbestos fibers traveled through the air and deposited in these trees." (7/29/09 Spear Dep. at 174-75 (Ex. 10).) However, that is not an issue the Court need address in the confirmation proceedings. It has absolutely no bearing on the issue of discrimination under the TDP.

3. Dr. Spear's opinions lack any reliable basis, and in many instances are completely outside his area of expertise.

Dr. Spear's opinions are also unreliable, and in many instances he completely lacks the necessary qualifications to offer them. For example, while Dr. Spear indicated during his deposition that he intended to offer opinions regarding the allegedly distinct nature of pleural disease in the Libby community, he plainly lacks the necessary qualifications to do so. By his own admission, Dr. Spear is not a medical doctor, a toxicologist, or an epidemiologist. (7/29/09 Spear Dep. at 210 (Ex. 10).) Moreover, he lacks any reliable basis for such opinions. While Dr. Spear identified several studies during his deposition that he claimed support his opinions, after discussing the findings of each study, Dr. Spear conceded that the only study that was actually relevant to his opinions was the Whitehouse observational study, which as discussed above, is fundamentally unreliable. The other basis of his opinion, his conversations with Dr. Black, is also insufficient. As a threshold matter, Dr. Spear cannot confer medical qualifications upon himself by simply consulting with a physician. Moreover, while Dr. Spear was under the impression that Dr. Black was a pulmonary specialist, in fact Dr. Black is a pediatrician who has never had any formal training in epidemiology, pulmonary medicine, or radiology. (7/29/09 Spear Dep. at 56-58 (Ex. 10); *see* 3/19/09 Whitehouse Dep. at 42-43 (Ex. 6)) Dr. Spear's foray into the world of medicine should be short lived.

Finally, Dr. Spear's suggestion that there were community exposures in Libby from asbestos imbedded in tree bark, aside from being categorically irrelevant to any issue, is completely unsupported. (12/29/08 Spear Report at 1-2 (Ex. 3).) At his deposition, Dr. Spear acknowledged that he could not offer any opinion "as to what the potential airborne exposures would be from these trees." (7/29/09 Spear Dep. at 174-75 (Ex. 3).) Moreover, Dr. Spear conceded that the air sampling he conducted in the forest occurred in a restricted zone and was a

"worse case" scenario that could not be extrapolated to potential exposures that occur outside of the restricted zone or in the Libby forest as a whole. (*Id.* at 184-87.) Accordingly, Dr. Spear cannot offer a reliable opinion about potential exposures based on his unrepresentative sampling.

CONCLUSION

For the foregoing reasons, the Plan Proponents respectfully request that the Court preclude the Libby Claimants' experts from testifying at the Confirmation Hearing.

Dated: August 13, 2009

Respectfully submitted,

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